

110TH CONGRESS
1ST SESSION

S. 1445

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish, promote, and support a comprehensive prevention, research, and medical management referral program for hepatitis C virus infection.

IN THE SENATE OF THE UNITED STATES

MAY 22, 2007

Mr. KENNEDY (for himself and Mrs. HUTCHISON) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish, promote, and support a comprehensive prevention, research, and medical management referral program for hepatitis C virus infection.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Hepatitis C Epidemic
5 Control and Prevention Act”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

1 (1) Approximately 5,000,000 Americans are in-
2 fected with the hepatitis C virus (referred to in this
3 section as “HCV”), and more than 3,000,000 Amer-
4 icans are chronically infected, leading the Centers
5 for Disease Control and Prevention (referred to in
6 this section as the “CDC”) to recognize HCV as the
7 Nation’s most common chronic blood-borne virus in-
8 fection.

9 (2) According to the CDC, nearly 2 percent of
10 the population of the United States have been in-
11 fected with HCV.

12 (3) The CDC conservatively estimates that ap-
13 proximately 30,000 Americans are newly infected
14 with HCV each year, and that number has been
15 growing since 2001.

16 (4) HCV infection, in the United States, is the
17 most common cause of chronic liver disease, liver
18 cirrhosis, and liver cancer, the most common indica-
19 tion for liver transplant, and the leading cause of
20 death in people with HIV/AIDS. In addition, there
21 may be links between HCV and certain other dis-
22 eases, given that a high number of people infected
23 with HCV also suffer from type 2 diabetes,
24 lymphoma, thyroid and certain blood disorders, and
25 autoimmune disease. Moreover, methamphetamine

1 abuse—which is a matter of increasing concern to
2 Congress and public health officials across the coun-
3 try—is recognized by the National Institute on Drug
4 Abuse to be inextricably linked to HCV.

5 (5) The majority of individuals infected with
6 HCV are unaware of their infection. Individuals in-
7 fected with HCV serve as a source of transmission
8 to others and, since few individuals are aware they
9 are infected, they are unlikely to take precautions to
10 prevent the spread or exacerbation of their infection.

11 (6) There is no vaccine available to prevent
12 HCV infection.

13 (7) Treatments are available that can eradicate
14 the disease in approximately 50 percent of those who
15 are treated, and behavioral changes can slow the
16 progression of the disease.

17 (8) Conservative estimates place the costs of di-
18 rect medical expenses for HCV at more than
19 \$1,000,000,000 in the United States annually, and
20 such costs will undoubtedly increase in the absence
21 of expanded prevention and treatment efforts.

22 (9) To combat the HCV epidemic in the United
23 States, the CDC developed Recommendations for
24 Prevention and Control of Hepatitis C Virus (HCV)
25 Infection and HCV-Related Chronic Disease in 1998

1 and the National Hepatitis C Prevention Strategy in
2 2001, and the National Institutes of Health con-
3 vened Consensus Development Conferences on the
4 Management of Hepatitis C in 1997 and 2002.
5 These recommendations and guidelines provide a
6 framework for HCV prevention, control, research,
7 and medical management referral programs.

8 (10) The Department of Veterans Affairs (re-
9 ferred to in this paragraph as the “VA”), which
10 cares for more people infected with HCV than any
11 other health care system, is the Nation’s leader in
12 HCV screening, testing, and treatment. Since 1998,
13 it has been the VA’s policy to screen for HCV risk
14 factors all veterans receiving VA health care, and
15 the VA currently recommends testing for all those
16 who are found to be “at risk” for the virus and for
17 all others who wish to be tested. In fiscal year 2004,
18 over 98 percent of VA patients had been screened
19 for HCV risk factors, and over 90 percent of those
20 “at risk” were tested. For all veterans who test posi-
21 tive for HCV and enroll in VA medical care, the VA
22 offers medications that can help HCV or its com-
23 plications. The VA also has programs for HCV pa-
24 tient and provider education, clinical care, data-
25 based quality improvement, and research, and it has

1 4 Hepatitis C Resource Centers to develop and dis-
 2 seminate innovative practices and tools to improve
 3 patient care. This comprehensive program should be
 4 commended and could potentially serve as a model
 5 for future HCV programs.

6 (11) Federal support is necessary to increase
 7 knowledge and awareness of HCV and to assist
 8 State and local prevention and control efforts.

9 **SEC. 3. PREVENTION, CONTROL, AND MEDICAL MANAGE-**
 10 **MENT OF HEPATITIS C.**

11 Title III of the Public Health Service Act (42 U.S.C.
 12 241 et seq.) is amended by adding at the end the fol-
 13 lowing:

14 **“PART S—PREVENTION, CONTROL, AND MEDICAL**
 15 **MANAGEMENT OF HEPATITIS C**

16 **“SEC. 399II. FEDERAL PLAN FOR THE PREVENTION, CON-**
 17 **TROL, AND MEDICAL MANAGEMENT OF HEPA-**
 18 **TITIS C.**

19 “(a) IN GENERAL.—The Secretary shall develop and
 20 implement a plan for the prevention, control, and medical
 21 management of the hepatitis C virus (referred to in this
 22 part as ‘HCV’) that includes strategies for education and
 23 training, surveillance and early detection, and research.

24 “(b) INPUT IN DEVELOPMENT OF PLAN.—In devel-
 25 oping the plan under subsection (a), the Secretary shall—

“(1) be guided by existing recommendations of the Centers for Disease Control and Prevention (referred to in this part as the ‘CDC’) and the National Institutes of Health, and the comprehensive HCV programs that have been implemented by the Department of Veterans Affairs, including the Hepatitis C Resource Center program; and

“(2) consult with—

“(A) the Director of the CDC;

“(B) the Director of the National Institutes of Health;

“(C) the Administrator of the Health Resources and Services Administration;

“(D) the heads of other Federal agencies or offices providing services to individuals with HCV infections or the functions of which otherwise involve HCV;

“(E) medical advisory bodies that address issues related to HCV; and

“(F) the public, including—

“(i) individuals infected with the HCV; and

“(ii) advocates concerned with issues related to HCV.

“(c) BIENNIAL ASSESSMENT OF PLAN.—

1 “(1) IN GENERAL.—The Secretary shall con-
2 duct a biennial assessment of the plan developed
3 under subsection (a) for the purpose of incor-
4 porating into such plan new knowledge or observa-
5 tions relating to HCV and chronic HCV (such as
6 knowledge and observations that may be derived
7 from clinical, laboratory, and epidemiological re-
8 search and disease detection, prevention, and surveil-
9 lance outcomes) and addressing gaps in the coverage
10 or effectiveness of the plan.

11 “(2) PUBLICATION OF NOTICE OF ASSESS-
12 MENTS.—Not later than October 1 of the first even
13 numbered year beginning after the date of enact-
14 ment of the Hepatitis C Epidemic Control and Pre-
15 vention Act, and October 1 of each even numbered
16 year thereafter, the Secretary shall publish in the
17 Federal Register a notice of the results of the as-
18 sessments conducted under paragraph (1). Such no-
19 tice shall include—

20 “(A) a description of any revisions to the
21 plan developed under subsection (a) as a result
22 of the assessment;

23 “(B) an explanation of the basis for any
24 such revisions, including the ways in which such
25 revisions can reasonably be expected to further

1 promote the original goals and objectives of the
 2 plan; and

3 “(C) in the case of a determination by the
 4 Secretary that the plan does not need revision,
 5 an explanation of the basis for such determina-
 6 tion.

7 **“SEC. 399JJ. ELEMENTS OF THE FEDERAL PLAN FOR THE**
 8 **PREVENTION, CONTROL, AND MEDICAL MAN-**
 9 **AGEMENT OF HEPATITIS C.**

10 “(a) EDUCATION AND TRAINING.—The Secretary,
 11 acting through the Director of the CDC, shall implement
 12 programs to increase awareness and enhance knowledge
 13 and understanding of HCV. Such programs shall in-
 14 clude—

15 “(1) the conduct of health education, public
 16 awareness campaigns, and community outreach ac-
 17 tivities to promote public awareness and knowledge
 18 about risk factors, the transmission and prevention
 19 of infection with HCV, the value of screening for the
 20 early detection of HCV infection, and options avail-
 21 able for the treatment of chronic HCV;

22 “(2) the training of healthcare professionals re-
 23 garding the prevention, detection, and medical man-
 24 agement of the hepatitis B virus (referred to in this
 25 part as ‘HBV’) and HCV, and the importance of

1 vaccinating HCV-infected individuals and those at
 2 risk for HCV infection against the hepatitis A virus
 3 and HBV; and

4 “(3) the development and distribution of cur-
 5 ricula (including information relating to the special
 6 needs of individuals infected with HBV or HCV,
 7 such as the importance of early intervention and
 8 treatment and the recognition of psychosocial needs)
 9 for individuals providing hepatitis counseling, as well
 10 as support for the implementation of such curricula
 11 by State and local public health agencies.

12 “(b) EARLY DETECTION AND SURVEILLANCE.—

13 “(1) IN GENERAL.—The Secretary, acting
 14 through the Director of the CDC, shall support ac-
 15 tivities described in paragraph (2) to promote the
 16 early detection of HCV infection, identify risk fac-
 17 tors for infection, and conduct surveillance of HCV
 18 infection trends.

19 “(2) ACTIVITIES.—

20 “(A) VOLUNTARY TESTING PROGRAMS.—

21 “(i) IN GENERAL.—The Secretary
 22 shall support and promote the development
 23 of State, local, and tribal voluntary HCV
 24 testing programs to aid in the early identi-
 25 fication of infected individuals.

1 “(ii) CONFIDENTIALITY OF TEST RE-
 2 SULTS.—The results of a HCV test con-
 3 ducted by a testing program developed or
 4 supported under this subparagraph shall
 5 be considered protected health information
 6 (in a manner consistent with regulations
 7 promulgated under section 264(c) of the
 8 Health Insurance Portability and Account-
 9 ability Act of 1996 and may not be used
 10 for any of the following:

11 “(I) Issues relating to health in-
 12 surance.

13 “(II) To screen or determine
 14 suitability for employment.

15 “(III) To discharge a person
 16 from employment.

17 “(B) COUNSELING REGARDING VIRAL HEP-
 18 ATITIS.—The Secretary shall support State,
 19 local, and tribal programs in a wide variety of
 20 settings, including those providing primary and
 21 specialty healthcare services in nonprofit private
 22 and public sectors, to—

23 “(i) provide individuals with informa-
 24 tion about ongoing risk factors for HCV
 25 infection with client-centered education

1 and counseling that concentrates on chang-
2 ing behaviors that place them at risk for
3 infection; and

4 “(ii) provide individuals infected with
5 HCV with education and counseling to re-
6 duce the risk of harm to themselves and
7 transmission of the virus to others.

8 “(C) VACCINATION AGAINST VIRAL HEPA-
9 TITIS.—With respect to individuals infected, or
10 at risk for infection, with HCV, the Secretary
11 shall provide for—

12 “(i) the vaccination of such individ-
13 uals against hepatitis A virus, HBV, and
14 other infectious diseases, as appropriate,
15 for which such individuals may be at in-
16 creased risk; and

17 “(ii) the counseling of such individuals
18 regarding hepatitis A, HBV, and other
19 viral hepatides.

20 “(D) MEDICAL REFERRAL.—The Secretary
21 shall support—

22 “(i) referral of persons infected with
23 or at risk for HCV, for drug or alcohol
24 abuse treatment where appropriate; and

1 “(ii) referral of persons infected with
2 HCV—

3 “(I) for medical evaluation to de-
4 termine their stage of chronic HCV
5 and suitability for antiviral treatment;
6 and

7 “(II) for ongoing medical man-
8 agement of HCV.

9 “(3) HEPATITIS C COORDINATORS.—The Sec-
10 retary, acting through the Director of the CDC,
11 shall, upon request, provide a Hepatitis C Coordi-
12 nator to a State health department in order to en-
13 hance the management, networking, and technical
14 expertise needed to ensure successful integration of
15 HCV prevention and control activities into existing
16 public health programs.

17 “(c) SURVEILLANCE AND EPIDEMIOLOGY.—

18 “(1) IN GENERAL.—The Secretary shall pro-
19 mote and support the establishment and mainte-
20 nance of State HCV surveillance databases, in order
21 to—

22 “(A) identify risk factors for HCV infec-
23 tion;

24 “(B) identify trends in the incidence of
25 acute and chronic HCV;

1 “(C) identify trends in the prevalence of
2 HCV infection among groups that may be dis-
3 proportionately affected by HCV, including in-
4 dividuals living with HIV, military veterans,
5 emergency first responders, racial or ethnic mi-
6 norities, and individuals who engage in high
7 risk behaviors, such as intravenous drug use;
8 and

9 “(D) assess and improve HCV infection
10 prevention programs.

11 “(2) CONFIDENTIALITY.—Information con-
12 tained in the databases under paragraph (1) shall be
13 de-identified in a manner consistent with regulations
14 under section 264(c) of the Health Insurance Port-
15 ability and Accountability Act of 1996.

16 “(d) RESEARCH NETWORK.—The Secretary, acting
17 through the Director of the CDC and the Director of the
18 National Institutes of Health, shall—

19 “(1) conduct epidemiologic research to identify
20 best practices for HCV prevention;

21 “(2) establish and support a Hepatitis C Clin-
22 ical Research Network for the purpose of conducting
23 research related to the treatment and medical man-
24 agement of HCV; and

1 “(3) conduct basic research to identify new ap-
2 proaches to prevention (such as vaccines) and treat-
3 ment for HCV.

4 “(e) REFERRAL FOR MEDICAL MANAGEMENT OF
5 CHRONIC HCV.—The Secretary shall support and pro-
6 mote State, local, and tribal programs to provide HCV-
7 positive individuals with referral for medical evaluation
8 and management, including currently recommended
9 antiviral therapy when appropriate.

10 “(f) UNDERSERVED AND DISPROPORTIONATELY AF-
11 FECTED POPULATIONS.—In carrying out this section, the
12 Secretary shall provide expanded support for individuals
13 with limited access to health education, testing, and
14 healthcare services and groups that may be disproportion-
15 ately affected by HCV.

16 “(g) EVALUATION OF PROGRAM.—The Secretary
17 shall develop benchmarks for evaluating the effectiveness
18 of the programs and activities conducted under this sec-
19 tion and make determinations as to whether such bench-
20 marks have been achieved.

21 **“SEC. 399KK. GRANTS.**

22 “(a) IN GENERAL.—The Secretary may award grants
23 to, or enter into contracts or cooperative agreements with,
24 States, political subdivisions of States, Indian tribes, or

1 nonprofit entities that have special expertise relating to
2 HCV, to carry out activities under this part.

3 “(b) APPLICATION.—To be eligible for a grant, con-
4 tract, or cooperative agreement under subsection (a), an
5 entity shall prepare and submit to the Secretary an appli-
6 cation at such time, in such manner, and containing such
7 information as the Secretary may require.

8 **“SEC. 399LL. AUTHORIZATION OF APPROPRIATIONS.**

9 “There are authorized to be appropriated to carry out
10 this part \$90,000,000 for fiscal year 2008, and
11 \$72,000,000 for each of fiscal years 2009 through 2012.”.

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